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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,262	04/02/2008	**Ronald P. Lesser**	61612(71699)	9788

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EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	**PAPER NUMBER**
3766	

MAIL DATE	DELIVERY MODE
09/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,262	LESSER ET AL.	
	Examiner	Art Unit	
	Kennedy J. Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-10,29-35,37,38,40 and 62-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-10,29-35,37,38,40 and 62-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/18/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 10, 32 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Eckerson (Pat. No. 4,865,048).

See the text abridging cols. 1 and 2, as well as col. 2, lines 60-69.

3. Claims 1, 2, 5, 29, 30, 40 and 62-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Marchal et al. (Pat. No. 6,853,862).

Regarding claim 1 and claims with similar limitations, Marchal et al. disclose a method for treating nausea and/or vomiting (see col. 6, lines 19-67), comprising the step of: applying electrical current from an external current source (see col. 4, lines 19-25, col. 5, lines 39-50, etc.) to a vagus nerve of a patient (see col. 3, lines 34-63) to reduce nausea and/or vomiting.

Regarding claims 29 and 30, Marchal et al. disclose that pregnant women with morning sickness who experience nausea and vomiting may benefit from vagus nerve stimulation (see for example col. 6, lines 25-38). It is considered inherent that if one is

attempting to treat a pregnant woman suffering from nausea and/or vomiting, one must first select and/or identify the woman.

Regarding claim 62, note the text abridging cols. 5 and 6.

Regarding claim 63, note col. 6, lines 3-24.

Regarding claim 64, the examiner considers the preset pulse width to constitute a turning on and off of the stimulation at predetermined times (e.g., at a specific period and frequency).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 5-9 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckerson.

Regarding claim 5, while Eckerson states that the electrodes are surface electrodes, the examiner takes Official Notice that it is old and well-known in the medical nerve stimulator arts to place electrodes either on the surface for non-invasive placement, or implanted within the body for chronic stimulation. The decision is clearly application dependent. For instance, patients requiring only short-term treatment may prefer skin placement of the electrodes to avoid the unnecessary trauma of surgery, while those requiring chronic treatment may opt for implant of the electrodes to avoid unsightly wires and the inconvenience and potential embarrassment of wearing a contraption for long periods of time. Patients suffering from mental or physical disabilities might also benefit from an implanted system not requiring conscious action to properly place the apparatus and control the stimulus treatment times.

Regarding claims 6-9, the examiner takes Official Notice that inductively controlled implantable devices are old and well-known in the medical arts. Such a system allows for non-invasive transmission of power and data to and/or from the implant without the need for invasive conductors which are prone to infection, and allows the implant to operate independently of any battery or implanted power source. Said systems also allow for the recharging of rechargeable batteries, thus negating the need to surgically remove the battery when the charge has been depleted.

Regarding claim 62, while Eckerson does not explicitly state that the stimulation is actuated manually, Eckerson does disclose that the patient may control the amount of time that the system is activated (see for example col. 2, lines 13-29, col. 3, lines 32-37, etc.). Common sense would indicate that if the patient has control over the therapy

length, the patient would need to have the ability to manually actuate and deactivate stimulation –especially over extended periods of treatment and at-home care where medical personnel may not be available when symptoms arise. Such a feature would have been considered obvious to those of ordinary skill in the art since it would allow the patient an effective measure of control over his/her treatment.

7. Claims 6-9, 31, 33 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchal et al..

Regarding claims 6-9, 31, 33 and 65, the examiner takes Official Notice that inductively controlled implantable devices are old and well-known in the medical arts. Such a system allows for non-invasive transmission of power and data to and/or from the implant without the need for invasive conductors which are prone to infection, and allows the implant to operate independently of any battery or implanted power source. Said systems also allow for the recharging of rechargeable batteries, thus negating the need to surgically remove the battery when the charge has been depleted.

8. Claims 10 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchal et al. in view of Barrett et al. (Pat. No. 6,609,025).

Regarding claim 10 with similar comments applying to claim 32, while Marchal et al. disclose that the stimulator may reside outside the patient (col. 4, lines 19-25), they do not explicitly state that the electrodes are placed on the skin. Barrett et al., however, discloses that the vagus nerve may be stimulated directly (i.e., with an electrode cuff placed about the nerve), indirectly from an implanted position (i.e., with an electrode implanted remote from the vagus nerve), or indirectly and non-invasively (see col. 7,

lines 54-67). By definition a non-invasively placed electrode must reside on the skin. Given the fact that those of ordinary skill in the art recognize that the vagus nerve may be effectively stimulated from a variety of electrode locations including both invasive and non-invasive locations, those of ordinary skill in the art would have considered the exact placement of the electrode to be one of obvious design with the condition and needs of the patient dictating the most appropriate site from which to base stimulation. As argued above, patients requiring only short-term treatment may prefer skin placement of the electrodes to avoid the unnecessary trauma of surgery, while those requiring chronic treatment may opt for implant of the electrodes to avoid unsightly wires and the inconvenience and potential embarrassment of wearing a contraption for long periods of time. Patients suffering from mental or physical disabilities might also benefit from an implanted system not requiring conscious action to properly place the apparatus and control the stimulus treatment times. As can be seen, a host of factors may influence electrode location, with careful consultation between the surgeon and individual patient dictating the most appropriate stimulation site.

9. Claims 34, 35, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchal et al. in view of Bertolucci (Pat. No. 4,981,146).

Marchal et al. do not explicitly discuss application of the method to chemotherapy patients or patients suffering from motion sickness. Common sense would indicate to one of ordinary skill in the art that any system capable of reducing nausea and/or vomiting for pregnant women would be useful to treat chemotherapy and motion sickness patients since these patients frequently suffer from nausea and vomiting as

well. In the very least it would have been reasonable to try the method of Marchal et al. on such patients with a reasonable expectation for success since one would expect substantially similar symptoms to be treatable with substantially similar treatments.

In any event, Bertolucci discloses that chemotherapy patients and those suffering from motion sickness may benefit from nerve stimulation in the treatment of nausea and/or vomiting. To therefore apply the method of Marchal et al. to chemotherapy and motion sickness patients would have been considered obvious by those of ordinary skill in the art.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy J. Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766

KJS
September 7, 2010